MAY 26 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Direct HDL Cholesterol Method for ADVIA® Modular System (IMS)™

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K050632

1. Intended Use

This *in vitro* method is intended to quantitatively measure HDL Cholesterol in human serum and plasma on the Bayer ADVIA® IMS systems. Measurements of HDL Cholesterol are used in assessing cardiovascular risk.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Bayer ADVIA 1650 Direct HDL Cholesterol	08058065	00309530 (B03-4763-01)

3. Device / Method

Product Name	Reagent Part #	Calibrator Part #
ADVIA IMS Direct HDL Cholesterol	07986694	00309530 (B03-4763-01)

4. Performance

A. Imprecision

ADVIA IMS	
Level mg/dL	Total CV (%)
37.04	3.3
54.84	1.9
82.55	1.8

ADVIA 1650	
Level mg/dL	Total CV(%)
36.15	2.6
55.00	1.9
76.92	1.9

C. Correlation (Y=ADVIA IMS, X = Comparison system)

Specimen type	Comparison System (X)	N	Regression Equation	Syx mg/dL	R	IMS Sample Range mg/dL
Serum	ADVIA 1650	100	Y= 0.986X + 1.16	2.29	0.988	15 to 88

D. Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	HDL Cholesterol Concentration (mg/dL)	Effect (% change)
Bilirubin (unconjugated)	30	44.3	-1.1%
Bilirubin (conjugated)	20	46.5	-7.3%
Hemoglobin	500	46.2	-9.5%
Lipids (Intralipid)	1000	45.0	-4.9%

E. Analytical Range

7 to 90 mg/dL.

3/4/2005

Andres Holle
Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York, 10591 - 5097

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Andres Holle
Manager, Regulatory Affairs
Bayer HealthCare
Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591

MAY 26 2005

Re: k050632
Trade/Device Name: Direct HDL Cholesterol for the ADVIA IMS
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I
Product Code: LBS
Dated: March 4, 2005
Received: March 9, 2005

Dear Mr. Holle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K050632

Device Name: Direct HDL Cholesterol for the ADVIA IMS

Indications for Use:

The *Bayer ADVIA IMS* Direct HDL Cholesterol (D-HDL) method is for *in vitro* diagnostic use to measure HDL Cholesterol in human serum and plasma. Such measurements are used in the risk assessment of cardiovascular diseases.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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